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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,411	03/01/2002	Gary P. Schroth	9584-030-999	6226

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EXAMINER
SITTON, JEHANNE SOUAYA

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,411	SCHROTH, GARY P.	
	Examiner	Art Unit	
	Jehanne S Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-7,9-12 and 21-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-7,9-12 and 21-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 1-2, 5-7, 9-12, and newly added claims 21-25 are pending in the instant application and are currently under examination. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are newly applied, as necessitated by amendment. They constitute the complete set being presently applied to the instant Application. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 1-12 under 35 USC 112/2nd paragraph, made in section 6 of the previous office action, is moot in view of the cancellation of claims 3 and 4, and the amendment to claim 6.

4. The rejections of claims 1-12 under 35 USC 102(b) as being anticipated, in the alternative, by Benner and by Collins et al, made in the previous office action at sections 8 and 10, respectively, are withdrawn in view of the amendments to claims 1, 6, and 11. Particularly, claim 1 was amended to recite that the coded test unit comprises a coding oligonucleotide and a test moiety, that the decoding oligonucleotide is complementary to the coding oligonucleotide, that the plurality of coded test units are contacted with the decoding oligonucleotide, and that the

coded test unit is identified from the plurality of coded test units by the production of a detectable hybridization signal in the contacting step.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-2, 5-7, 9, 10, 12, and 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Grenier (Grenier et al; US Pregrant Publication 2004/0106108).

Grenier teaches a method involving detection of hybridization of a target oligonucleotide to capture probes immobilized on a solid support (with regard to instant claims 1, 6, 23) (see abstract, page 1, para 0003). Grenier teaches that the target oligonucleotide comprises a tagging sequence (decoding oligonucleotide) which is complementary to a molecular recognition sequence on the capture probe (coded test unit) (see page 1, para 0003; page 2, para 0035). Grenier teaches that the capture probes have different molecular recognition sequences (plurality of coded test units) (see page 3, para 0044). Grenier teaches that the capture oligonucleotides are disposed on the solid support in a manner which permits the identification of the capture oligonucleotide (see page 3, para 0040). Grenier teaches that the target includes a reporter so that hybridization can be determined (decoding oligonucleotide produces a detectable

hybridization signal sufficient to distinguish the coded test unit from the plurality of coded test units, coded test unit is identified from the plurality of coded test units by the production of a detectable hybridization signal in the contacting step). Grenier teaches that the tagging sequence of the target as well as the capture probe can contain non standard bases (page 4, para 0046) such as iso-C, iso-G, K, X, H, J, M, and N (see page 4, para 0052) (with regard to instant claim 5).

With regard to claim 2, Grenier teaches that capture probes are provided on the support and can be used to analyze a sample for multiple analyte specific sequences (identifying a first molecule in the plurality of test units and identifying a second molecule in the plurality of coded test units) (see page 3, para 0040).

With regard to claim 7, Grenier teaches that that a single solid support is typically divided into individual regions with capture oligonucleotides disposed on the support in each region, or on each particle support and that the capture oligonucleotides of different regions have different sequences (see page 5, para 0058) (identifying a first substrate and a second substrate).

With regard to claim 9, the claim requires that the test moiety is an oligonucleotide. With regard to claim 10, the claim requires that a single polynucleotide comprise the test moiety and the coding oligonucleotide. With regard to claim 22, the claim requires that the test moiety is covalently linked o the coding oligonucleotide. The capture oligonucleotides of Grenier can be considered to comprise a nucleic acid region which is the test moiety and a nucleic acid region with is the coding oligonucleotide.

With regard to claim 12, Grenier teaches that the solid support with different regions can form an array (page 5, para 0059).

With regard to claim 24, the claim stipulates that the test moiety and coding oligonucleotide of the coded test unit are non identical to test moiety and coding oligonucleotide of other coded test units in the plurality. The capture oligonucleotides of Grenier can be considered to comprise a nucleic acid region which is the test moiety and a nucleic acid region with is the coding oligonucleotide. As Grenier teaches that different capture oligonucleotide have different sequences, Grenier inherently teaches the limitations of claim 24.

With regard to claim 21, alternatively the capture oligonucleotide taught by Grenier can be considered the coding oligonucleotide and the linkage to the support can be considered to be the test moiety. Grenier specifically teaches that the capture oligonucleotides are optionally covalently linked to the solid support or attached via a linker such as streptavidin, an antibody, an antigen, etc, which can be considered the test moiety (see page 6, para 0066, para 0068) (test moiety is a polypeptide).

Claim Rejections - 35 USC § 103

7. Claims 11 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grenier in view of Cronin (Cronin et al; Human Mutation, vol. 7, pages 244-255, 1996).

Grenier teaches a method involving detection of hybridization of a target oligonucleotide to capture probes immobilized on a solid support (with regard to instant claims 1, 6, 23) (see abstract, page 1, para 0003). Grenier teaches that the target oligonucleotide comprises a tagging sequence (decoding oligonucleotide) which is complementary to a molecular recognition sequence on the capture probe (coded test unit) (see page 1, para 0003; page 2, para 0035). Grenier teaches that the capture probes have different molecular recognition sequences (plurality

of coded test units) (see page 3, para 0044). Grenier teaches that the capture oligonucleotides are disposed on the solid support in a manner which permits the identification of the capture oligonucleotide (see page 3, para 0040). Grenier teaches that the target includes a reporter so that hybridization can be determined (decoding oligonucleotide produces a detectable hybridization signal sufficient to distinguish the coded test unit from the plurality of coded test units, coded test unit is identified from the plurality of coded test units by the production of a detectable hybridization signal in the contacting step). Grenier teaches that the tagging sequence of the target as well as the capture probe can contain non standard bases (page 4, para 0046) such as iso-C, isoG, K, X, H, J, M, and N (see page 4, para 0052).

Grenier teaches that the capture probes can be covalently linked to the solid support (see page 6, para 0066). Grenier also teaches that SNPs can be detected using the different capture oligonucleotides. Grenier teaches that allele specific primers can be used for amplification of the target and that such can be detected by hybridizing to an allele specific capture oligonucleotide (see pages 8-9, para 0095). However, Grenier does not provide any specific details regarding the arrangement of the capture oligonucleotides on the substrate for such purposes. Further, Grenier does not teach a coded test unit that comprises a test moiety that is a first polynucleotide or a coding oligonucleotide that is a second polynucleotide wherein each polynucleotide is independently linked to the solid substrate (instant claim 11) or generally a coded test unit that comprises a test moiety and a coding oligonucleotide which are each independently covalently linked to the solid substrate.

However, Cronin teaches that mutation probe arrays can be constructed such that a panel of specialized compact tiling arrays specific for mutations contain probes grouped in mutation

specific sets, each set being specific for a particular mutation (see page 246col. 2, first full para). Cronin exemplifies a probe array for detection of mutations in the Cystic Fibrosis gene. Cronin teaches that 37 mutations were assayed using 37 different mutation specific sets of probes on a support. The array contains sets of columns wherein paired probes in each set differ only at the mutant base (see figure 3, for example). Cronin teaches that target sequences are labeled (see page 246, col. 2). Cronin teaches that such tiling arrays allow for direct, side by side comparison of hybridization results of mutant and wild type probes and permits unambiguous assignment of heterozygous genotypes (see page 248, col. 2, last sentence). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to arrange the capture oligonucleotides in the method of identification of covalently linked capture probes on a solid support of Grenier with the arrangement of covalently linked capture probes of Cronin for the purpose of allowing assignment of particular alleles in target sequences and further allowing detection of mutations or SNPs at different positions in a single gene on a support. The ordinary artisan would have been motivated to arrange the array of capture probes of Grenier as taught by Cronin because Cronin teaches that the overlapping probe method allows cross confirmation of sequence assignments and unambiguous assignment of heterozygous genotypes. Claim 11 stipulates that the test moiety and coding oligonucleotide are separate polynucleotides that are independently linked to the solid substrate. However, in neither claims 1, 6, 9, 11 or 25 do the claims provide any specific limitation as to the identity of the test moiety in relation to the coding oligonucleotide; the claims have therefor been broadly construed. In the array and method of Grenier in view of Cronin, alternatively, each sub array or set of probes for a particular mutation can be considered a coded test unit, wherein the oligonucleotide capture

probe which is complementary to the allele specific tag on a particular target can be considered the coding oligonucleotide and the capture oligonucleotide that is not completely complementary to the target at a specific allelic position can be considered the test moiety. Hybridization of a target nucleic acid which comprises a mutation at position A to a set of capture probes which contain different allelic positions corresponding to position A, would identify the coded test unit (set of probes specific for different alleles of position A) and would distinguish the set of probes (coded test unit) from the plurality of other sets of probes to mutations at positions B, C, D, etc (plurality of coded test units) on the solid support. As such, the test moiety and the coding oligonucleotide are also independently covalently attached to the solid substrate (claim 25) (both Grenier and Cronin teach covalent linkage of the capture probe to the substrate).

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. No claims are allowable over the cited prior art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jehanne Sitton

Jehanne Sitton
Primary Examiner
Art Unit 1634

11/24/04